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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,674	10/25/2001	Robert C. Ladner	DYAX/002CIP2	2458

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FISH & NEAVE IP GROUP
ROPES & GRAY LLP
1251 AVENUE OF THE AMERICAS FL C3
NEW YORK, NY 10020-1105

EXAMINER	
EPPERSON, JON D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,674	LADNER ET AL.	
	Examiner	Art Unit	
	Jon D Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-116* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-116* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 19-32 (in part), 39-53 (in part), 54-58, 92-95, 108-112, 113 (in part) and 116 (in part) drawn to a method for "cleaving" and/or "preparing" nucleic acid including "immunoglobulin genes", classified variously in class 435, subclass 91.1, 91.4+, DIG 47.

II. Claims 3-10, 19-32 (in part), 33-38, 39-53 (in part), 59-61, 64-77, 99-104, 106, 107, 113 (in part) and 116 (in part) drawn to a method for "preparing a library comprising a collection of genetic packages" that "display" and/or "express" a member of a "diverse family of proteins", classified variously in class 435, subclass 5, 91.2+, DIG 3.

III. Claims 11-13, 17, 18, 19-32 (in part), 39-53 (in part), 62 and 114, drawn to a product described as a "library of genetic packages", classified variously in class 435, subclass 5, 478, DIG 24.

IV. Claims 14-16, 19-32 (in part), 39-53 (in part), 63 and 115 drawn to a product described as a "library of a collection of members of a diverse family of peptides" including "immunoglobulins", classified variously in class 435, subclass 6, 7.1, DIG 35.

V. Claims 78-91, 98, drawn to a product described as a nucleic acid "vector", classified variously in class 435, subclass 6, subclass 320.1.

2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I-V represent separate and patentably distinct inventions. Groups I-II are drawn to different methods and Groups III-V are drawn to a different product (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these products and methods have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group will support separate patents.

4. For Example, Groups I and II represent separate and patentably distinct methods. The methods are distinct because they use different steps, require different reagents and/or will produce different results. In the instant case, Group II requires "a genetic package" (e.g., phage) and/or a "protein" that is expressed by the genetic package, which is not required by Group I. Instead, Group I is drawn to the manipulation of "nucleic acids". In addition, the methods can be used for different purposes (e.g., the method of Group I could be used to make nucleic acids for "hybridization" experiments. Thus, Groups I and II are clearly distinct. In addition, searching the inventions of groups I and II together would impose a serious search burden. The inventions of Groups I and II have a separate status in the art as shown by their different classifications and/or divergent subject matter as shown above. Thus, the search would not be coextensive. For

example, journal articles devoted solely to polypeptides and/or expression of said polypeptide may not contain describe the polynucleotides (e.g., journals like Protein Journal, Protein Expression and Purification, etc.). Likewise, there may have been "classical" genetics papers, which had no knowledge of the polypeptide but spoke to only the manipulation of the genes.

5. Furthermore, Groups III-V represent separate and patentably distinct products. Groups III-V represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. For example, Groups III and IV require a "library", which is not required by Group V. In addition, Group III requires a "genetic package" that is not required by Group IV. Thus, a search for Groups III-V would not be coextensive. For example, vectors can be found in journals drawn to nucleic acids used in cloning that have nothing to do with the production of a library. In addition, a library of proteins can be found in journals drawn only to proteins. Thus a search burden exists.

6. Finally, if applicant were to argue that any of Groups I and II were somehow related to Group III-V as process of making and product made, the inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, (2) the product as claimed can be made by another materially different process (e.g., the oligonucleotide synthesis without restriction enzymes). Here, the process of Group I could be used to make another materially different product (e.g., hybridization probes and/or DNA chips). Likewise, the process of Group

II could be used to make affinity protein column purification systems and/or homing devices for drug delivery. In addition, the products of Groups III-V and be made using other materially different processes (e.g., the proteins and/or immunoglobulins can be made with ribosome display and the genetic packages can be made without the use of restriction enzymes).

7. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

8. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-V. Election is required as follows.

9. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of nucleic acid (see claims 1-2)

A. Single Stranded (see claim 1)
B. Partially double stranded (see claim 2)

Applicant must elect, for the purposes of search, a ***single species*** of nucleic acid from the list above i.e., A or B.

Subgroup 2: Species of restriction endonuclease (e.g., see claims 1 and 52)

Applicant must elect, for the purposes of search, a ***single species*** of restriction endonuclease (e.g., FokI).

Subgroup 3: Species of what nucleic acid encodes (e.g., see claims 19-30)

Applicant must elect, for the purposes of search, a ***single species*** of what the nucleic acid encodes e.g., human FR1. Please do not elect a broad category of molecules like immunoglobulin as more than one species would be erroneously elected. Please also indicate the nucleic acid source (i.e., human) and indicate whether it is a heavy or light chain, etc. Applicants must also indicate where the diversity occurs and whether it is synthetic or natural.

Subgroup 4: Species of derivation (e.g., see claims 31-32)

Applicant must elect, for the purposes of search, a ***single species*** of autoimmune disease e.g., lupus, erythematosus.

Subgroup 5: Species of isolated cells (see claim 20)

Applicant must elect, for the purposes of search, a ***single species*** of isolated cells e.g., blood cells, bone marrow cells.

Subgroup 6: Species of double stranded size (e.g., see claim 55)

Applicant must elect, for the purposes of search, a ***single species*** of double stranded size (e.g., between 2 and 15 bases).

Subgroup 7: Species of amplification (see claim 108)

Applicant must elect, for the purposes of search, a ***single species*** of amplification e.g., no amplification, amplification with geneRACE (e.g., see claim 38).

Subgroup 8: Species of temperature (see claim 42)

Applicant must elect, for the purposes of search, a ***single species*** of temperature e.g., 55°C.

Subgroup 9: Species of double-stranded portion length (see claims 112)

Applicant must elect, for the purposes of search, a ***single species*** of oligonucleotide length e.g., 20 bases.

Subgroup 10: Species of single stranded portion length (see claims 109)

Applicant must elect, for the purposes of search, a ***single species*** of length e.g., 2 bases.

10. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 3 is generic.

Subgroup 1: Species of nucleic acid (see claims 3-4)

A. Single Stranded (e.g., see claim 3)
B. Partially double stranded (e.g., see claim 4)

Applicant must elect, for the purposes of search, a ***single species*** of nucleic acid from the list above i.e., A or B.

Subgroup 2: Species of restriction endonuclease (e.g., see claims 1 and 52)

Applicant must elect, for the purposes of search, a ***single species*** of restriction endonuclease (e.g., FokI).

Subgroup 3: Species of what nucleic acid encodes (e.g., see claims 19-30)

Applicant must elect, for the purposes of search, a ***single species*** of what the nucleic acid encodes e.g., human FR1. Please do not elect a broad category of molecules like immunoglobulin as more than one species would be erroneously elected. Please also indicate the nucleic acid source (i.e., human) and indicate whether it is a heavy or light chain, etc. Applicants must also indicate where the diversity occurs and whether it is synthetic or natural.

Subgroup 4: Species of derivation (e.g., see claims 31-32)

Applicant must elect, for the purposes of search, a ***single species*** of autoimmune disease e.g., lupus, erythematosus.

Subgroup 5: Species of isolated cells (see claim 20)

Applicant must elect, for the purposes of search, a ***single species*** of isolated cells e.g., blood cells, bone marrow cells.

Subgroup 6: Species of double stranded size (e.g., see claim 55)

Applicant must elect, for the purposes of search, a ***single species*** of double stranded size (e.g., between 2 and 15 bases).

Subgroup 7: Species of amplification (see claim 38)

Applicant must elect, for the purposes of search, a ***single species*** of amplification e.g., no amplification, amplification with geneRACE.

Subgroup 8: Species of temperature (see claim 42)

Applicant must elect, for the purposes of search, a ***single species*** of temperature e.g., 55°C.

Subgroup 9: Species of double-stranded portion length (see claims 112)

Applicant must elect, for the purposes of search, a ***single species*** of oligonucleotide length e.g., 20 bases.

Subgroup 10: Species of single stranded portion length (see claims 109)

Applicant must elect, for the purposes of search, a ***single species*** of length e.g., 2 bases.

Subgroup 11: Species of genetic package (see claims 3-6)

Applicant must elect, for the purposes of search, a ***single species*** of genetic package e.g., phage.

11. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Claim 11 is generic.

Subgroup 1: Species of nucleic acid used to make library (see claims 1-2)

A. Single Stranded (see claim 1)
B. Partially double stranded (see claim 2)

Applicant must elect, for the purposes of search, a ***single species*** of nucleic acid from the list above i.e., A or B.

Subgroup 2: Species of restriction endonuclease used to make library (e.g., see claims 1 and 52)

Applicant must elect, for the purposes of search, a ***single species*** of restriction endonuclease (e.g., FokI).

Subgroup 3: Species of what nucleic acid encodes in library (e.g., see claims 19-30)

Applicant must elect, for the purposes of search, a ***single species*** of what the nucleic acid encodes e.g., human FR1. Please do not elect a broad category of molecules like immunoglobulin as more than one species would be erroneously elected. Please also indicate the nucleic acid source (i.e., human) and indicate whether it is a heavy or light chain, etc. Applicants must also indicate where the diversity occurs and whether it is synthetic or natural.

Subgroup 4: Species of derivation (e.g., see claims 31-32)

Applicant must elect, for the purposes of search, a ***single species*** of autoimmune disease e.g., lupus, erythematosus.

Subgroup 5: Species of isolated cells (see claim 20)

Applicant must elect, for the purposes of search, a ***single species*** of isolated cells e.g., blood cells, bone marrow cells.

Subgroup 6: Species of double stranded size (e.g., see claim 55)

Applicant must elect, for the purposes of search, a ***single species*** of double stranded size (e.g., between 2 and 15 bases).

Subgroup 7: Species of amplification (see claim 108)

Applicant must elect, for the purposes of search, a ***single species*** of amplification e.g., no amplification, amplification with geneRACE (e.g., see claim 38).

Subgroup 8: Species of temperature (see claim 42)

Applicant must elect, for the purposes of search, a ***single species*** of temperature e.g., 55°C.

Subgroup 9: Species of double-stranded portion length (see claims 112)

Applicant must elect, for the purposes of search, a ***single species*** of oligonucleotide length e.g., 20 bases.

Subgroup 10: Species of single stranded portion length (see claims 109)

Applicant must elect, for the purposes of search, a ***single species*** of length e.g., 2 bases.

Subgroup 11: Species of genetic package used to make library (see claims 3-6)

Applicant must elect, for the purposes of search, a ***single species*** of genetic package e.g., phage.

12. If applicant elects the invention of Group IV, applicant is required to elect from the following patentably distinct species. Claim 14 is generic.

Subgroup 1: Species of nucleic acid used to make library (see claims 1-2)

A. Single Stranded (see claim 1)
B. Partially double stranded (see claim 2)

Applicant must elect, for the purposes of search, a ***single species*** of nucleic acid from the list above i.e., A or B.

Subgroup 2: Species of restriction endonuclease used to make library (e.g., see claims 1 and 52)

Applicant must elect, for the purposes of search, a ***single species*** of restriction endonuclease (e.g., FokI).

Subgroup 3: Species of what nucleic acid encodes in library (e.g., see claims 19-30)

Applicant must elect, for the purposes of search, a ***single species*** of what the nucleic acid encodes e.g., human FR1. Please do not elect a broad category of molecules like immunoglobulin as more than one species would be erroneously elected. Please also indicate the nucleic acid source (i.e., human) and indicate whether it is a heavy or light chain, etc. Applicants must also indicate where the diversity occurs and whether it is synthetic or natural (e.g., see claims 96-97).

Subgroup 4: Species of derivation (e.g., see claims 31-32)

Applicant must elect, for the purposes of search, a ***single species*** of autoimmune disease e.g., lupus, erythematosus.

Subgroup 5: Species of isolated cells (see claim 20)

Applicant must elect, for the purposes of search, a ***single species*** of isolated cells e.g., blood cells, bone marrow cells.

Subgroup 6: Species of double stranded size (e.g., see claim 55)

Applicant must elect, for the purposes of search, a ***single species*** of double stranded size (e.g., between 2 and 15 bases).

Subgroup 7: Species of amplification (see claim 108)

Applicant must elect, for the purposes of search, a ***single species*** of amplification e.g., no amplification, amplification with geneRACE (e.g., see claim 38).

Subgroup 8: Species of temperature (see claim 42)

Applicant must elect, for the purposes of search, a ***single species*** of temperature e.g., 55°C.

Subgroup 9: Species of double-stranded portion length (see claims 112)

Applicant must elect, for the purposes of search, a ***single species*** of oligonucleotide length e.g., 20 bases.

Subgroup 10: Species of single stranded portion length (see claims 109)

Applicant must elect, for the purposes of search, a ***single species*** of length e.g., 2 bases.

13. If applicant elects the invention of Group V, applicant is required to elect from the following patentably distinct species. Claim 78 is generic.

Subgroup 1: Species of vector (e.g., see claims 78-87 and 89)

Applicant must elect, for the purposes of search, a ***single species*** of (e.g., encodes VHCH1 linked to trpIII. Please do not elect a broad class of molecules (e.g., Fab) as this will be held non-responsive. Please also indicate any anchor molecules that are encoded (e.g., pIII anchor).

14. **Please Note:** Applicants must disclose which claims read on the elected species (see paragraphs 15 and 16 below).

15. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

16. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

17. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a a rejection under 35 U.S.C. 103(a) of the other invention.

18. Applicant is advised that a reply to this requirement ***must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added***. An argument that a claim is allowable or that all claims are generic is considered ***nonresponsive*** unless accompanied by an election.

19. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, ***applicant must indicate which are readable upon the elected species***. MPEP § 809.02(a).

20. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

21. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

22. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

23. Finally, Applicant is reminded that where applicant elects claims directed to a product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
February 21, 2005